Claims

1. A dry powder inhaler device comprising a dry powder formulation comprising a pharmaceutically active agent, wherein upon actuation of the device, a dosing efficiency at 5μm of at least 70% is achieved.

2. A device as claimed in claim 1, wherein a dosing efficiency at 3μm of at least 60% is achieved

3. A device as claimed in claim 1, wherein a dosing efficiency at 2μm of preferably at least 40% is achieved.

4. A device as claimed in any of the preceding claims, wherein the dry powder composition was prepared using a method comprising co-spray drying the pharmaceutically active agent with a force control agent.

5. A device as claimed in claim 4, wherein the force control agent is an amino acid, a phospholipid or a metal stearate, and is preferably leucine.

6. A device as claimed in any of claims 4 or 5, wherein the active agent is spray dried using a spray drier comprising a means for producing droplets moving at a controlled velocity and of a predetermined size.

7. A device as claimed in claim 6, wherein the spray drier comprises an ultrasonic nebuliser.

8. A device as claimed in any one of claims 4-7, wherein the method comprises adjusting the moisture content of the spray dried particles.

9. A device as claimed in any one of claims 1-3, wherein composite active particles for use in the pharmaceutical composition are prepared using a method comprising jet milling active particles in the presence of particles of additive

material.

10. A device as claimed in claim 9, wherein the additive material comprises an amino acid, a metal stearate or a phospholipid.

11. A device as claimed in claim 10, wherein the additive material comprises one or more of leucine, isoleucine, lysine, valine, methionine, phenylalanine, and preferably leucine.

12. A device as claimed in any one of the preceding claims, wherein the device is an active device.

13. A device as claimed in any one of claims 1 to 11, wherein the device is a passive device.

14. A device as claimed in any one of the preceding claims, wherein the dry powder formulation is in pre-metered doses stored in one or more foil blisters.

15. A device as claimed in any one of the preceding claims, wherein the dry powder formulation has a fine particle dose of the emitted dose of at least 70%.

16. A device as claimed in claim 15, wherein the fine particle dose is at least 80%.

17. A device as claimed in any one of the preceding claims, wherein the dry powder formulation has a fine particle dose of the metered dose of at least 65%.

18. A device as claimed in claim 16, wherein the fine particle dose is at least 75%.

19. A device as claimed in any one of the preceding claims, wherein the dry powder formulation dispensed upon actuation produces a peak blood plasma level within 1 to 20 minutes of pulmonary inhalation.

20. A device as claimed in claim 19, wherein the peak blood plasma level within 1 to 10 minutes of pulmonary inhalation.

21. A device as claimed in any one of the preceding claims, wherein the dry powder formulation dispensed upon actuation produces the pharmacodynamic effect within 15 minutes of pulmonary inhalation.

22. A device as claimed in claim 21, wherein the effect is produced within 10 minutes of pulmonary inhalation.

23. A device as claimed in claim 21, wherein the effect is produced within 5 minutes of pulmonary inhalation.

24. A device as claimed in any one of the preceding claims, wherein the onset of the effect of the pharmaceutically active agent following pulmonary inhalation is twice as fast as the onset of the effect when the agent is administered via the oral route.

25. A device as claimed in claim 24, wherein the onset of the effect is three times faster than that achieved by administration via the oral route.

26. A device as claimed in claim 24, wherein the onset of the effect is five times faster than that achieved by administration via the oral route.

27. A device as claimed in claim 24, wherein the onset of the effect is eight times faster than that achieved by administration via the oral route.

28. A device as claimed in any one of the preceding claims, wherein the effect of the dry powder formulation following pulmonary inhalation is such that the dose of the pharmaceutically active agent is reduced by at least 50% compared to the dose required to have the same effect when administered via the oral route.

29. A device as claimed in claim 28, wherein the dose is reduced by at least 70%.

30. A device as claimed in claim 28, wherein the dose is reduced by at least 80%.

31. A device as claimed in claim 28, wherein the dose is reduced by at least 90%.

32. A device as claimed in any one of the preceding claims, wherein the administration of the dry powder formulation by pulmonary inhalation does not cause the adverse side effects normally associated with the administration of the pharmaceutically active agent via other routes.

33. A device as claimed in any one of the preceding claims, wherein the dry powder formulation is produced by a micronisation process.

34. A device as claimed in any one of the preceding claims, wherein the dry powder formulation has a tapped density of more than 0.1g/cc.

35. A device as claimed in claim 34, wherein the formulation has a tapped density of more than 0.2g/cc.

36. A device as claimed in claim 34, wherein the formulation has a tapped density of more than 0.5g/cc.

37. A device as claimed in any one of the preceding claims, wherein the pharmaceutically active agent has a systemic effect following administration by pulmonary inhalation.

38. A device as claimed in any one of the preceding claims, wherein the pharmaceutically active agent is a small molecule or a carbohydrate.

39. A device as claimed in any one of the preceding claims, wherein the dry powder formulation is processed without the use of an organic solvent.

40. A device as claimed in any one of the preceding claims, wherein the dry powder formulation is dry processed in the absence of any solvent.